K120591

APR 17 2012

5. 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92

plicant: Diamond Diagnostics Inc
333 Fiske Street
Holliston MA 01746

Contact Person: Kathy Cruz
Quality Assurance Manager
Phone: (508) 429-0450 ext. 358
Fax: (508) 429-0452

Date Prepared: January 26, 2012

Classification Name: Calibrator, secondary

Trade Name: Diamond Calibrators for Tokyo Boeki ISE Modules

Device Classification: 21 CFR 862.1150

Device Class: Class II

Classification Panel: Clinical Chemistry

Product Code: JIT

Intended Use:

Diamond Tokyo Boeki Calibrators are intended to serve as a direct replacement to Tokyo Boeki ISE Calibrators. Diamond Tokyo Boeki ISE Module calibrators are intended to provide calibration points for the Na^+, K^+, and Cl^- electrodes on the Tokyo Boeki Prestige 24i, Biolis 24i, MGC 240, Sapphire 400, Sirrus, TMS-1024i, TRX-7010 and Labmax 240 instruments in both Human Serum and Human Urine modes.

Description of Device:

Diamond Calibrator 1 consists of a buffered solution of electrolytes and preservative. It contains no human or biological materials. It is packaged in a foil bag with a draw tube and covered in a corrugated box. Each foil bag contains 420 ml of solution.

Diamond Calibrator 2 consists of a buffered solution of electrolytes and preservative. It contains no human or biological materials. It is packaged in a plastic bottle with a cap. Each plastic bottle contains 20 ml of solution.

Diamond Urine Calibrator is comprised of Urine Calibrator 1 and 2 which are not sold separately. Each box contains 10 ampules of Calibrator 1 in a tray and 10 ampules of Calibrator 2 in a separate tray.

Diamond Urine Calibrator 1 consists of a buffered solution of electrolytes and preservative. It contains no human or biological materials. It is packaged in glass ampule. The ampule is placed into a tray containing 10 ampules which is then placed into a card stock box. Each ampule contains 1.8 ml of solution.

Diamond Urine Calibrator 2 consists of a buffered solution of electrolytes and preservative. It contains no human or biological materials. It is packaged in glass ampule. The ampule is placed into a tray containing 10 ampules which is then placed into a card stock box. Each ampule contains 1.8 ml of solution.

Each calibrator is comprised of the following concentrations of analytes,

PN	ISE Module Calibrator	Na^+ mmol/L	K^+ mmol/L	Cl^- mmol/L
TB-20270477D	Calibrator 1	140 ± 2.0	4.00 ± 0.05	100 ± 2
TB-20270478D	Calibrator 2	160 ± 2.0	6.0 ± 0.05	120 ± 2

PN	ISE Module Calibrator	Na^+ mmol/L	K^+ mmol/L	Cl^- mmol/L
TB-20270480D	Urine Calibrator 1-2			
TB-20270480AD	Urine Calibrator 1	10 ± 0.5	1.50 ± 0.03	12 ± 0.5
TB-20270480BD	Urine Calibrator 2	60 ± 1.0	25.0 ± 1.0	85 ± 2

Predicate Device: Tokyo Boeki ISE Module Calibrators

Predicate 510(k) number(s): K040958

›mparison with predicate:

Characteristics	Diamond Calibrators for Tokyo Boeki ISE Module	Tokyo Boeki ISE Module Calibrators
Device	New	Predicate
510(k) Number		K040958
PN	TB-20270477D TB-20270478D TB-20270480D	20-27-0477 20-27-0478 20-27-0480
Product Type	Calibrators	same
Intended Use	For *in-vitro* diagnostics use to provide calibration points for the Na^+, K^+, and Cl^- electrodes on the Tokyo Boeki Prestige 24i, Biolis 24i, MGC 240, Sapphire 400, Sirrus, TMS-1024i, TRX-7010 and Labmax 240 instruments having an ISE Module	same
Matrix	Buffered solution of salts & preservatives Contains NO human or animal materials.	same
Packaging	Foil Bag, Plastic bottle, Glass Ampule	same
Color	Clear solution	same
Storage	18-25°C	same
Shelf Life for TB-20270477D	24 months	same
Shelf Life for TB-20270478D	24 months	same
Shelf Life for TB-20270480D	24 months	same

Summary of Analytical Tests:

a. Precision

Three samples each of Serum and Urine were analyzed. The samples are near the low, mid and high point of reference ranges. Within Run precision was calculated from 20 consecutive samples run between calibrations. Run to Run precision was calculated for 5 consecutive samples run between calibrations.

Serum Precision, Within Run

	Na^+			K^+			Cl^-		
	Low	Mid	High	Low	Mid	High	Low	Mid	High
Mean	118.04	142.94	154.64	3.93	5.08	5.92	92.35	110.38	118.43
SD	0.57	0.98	0.73	0.02	0.02	0.03	0.43	0.29	0.46
%CV	0.48	0.69	0.47	0.47	0.4	0.45	0.54	1.06	1.2
Spec	<1	<1	<1	<2	<2	<2	<1	<1	<1
P/F	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Serum Precision, Run to Run

	Na^+			K^+			Cl^-		
	Low	Mid	High	Low	Mid	High	Low	Mid	High
Mean	121.65	137.29	155.54	3.92	4.98	5.82	98.97	107.91	118.11
SD	1.21	1.03	1.12	0.02	0.05	0.07	0.68	0.92	0.72
%CV	0.99	0.75	0.72	0.54	1.06	1.2	0.69	0.85	0.61
Spec	<1	<1	<1	<2	<2	<2	<2	<2	<2
P/F	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Urine Precision, Within Run

	Na^+			K^+			Cl^-		
	Low	Mid	High	Low	Mid	High	Low	Mid	High
Mean	80.83	145.96	198.21	9.1	33.53	77.42	77.97	113.15	169.17
SD	1.9	1.47	1.96	0.05	0.16	0.32	2.49	1.05	1.91
%CV	2.36	1.01	0.99	0.55	0.48	0.42	3.19	0.93	1.13
Spec	<4	<4	<4	<4	<4	<4	<4	<4	<4
P/F	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Urine Precision, Run to Run

	Na^+			K^+			Cl^-		
	Low	Mid	High	Low	Mid	High	Low	Mid	High
Mean	80.71	172.26	207.53	8.99	32.09	80.64	67.63	118.21	170.1
SD	1.21	4.27	6.77	0.36	1.09	2.08	0.89	3.59	1.92
%CV	1.49	2.48	3.26	3.96	3.39	2.58	1.31	3.04	1.13
Spec	<4	<4	<4	<4	<4	<4	<4	<4	<4
P/F	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

b. Linearity

Linearity was evaluated by preparing stock solution with high concentrations of Na^+, K^+, and Cl^- in serum and urine. The stock solutions were diluted (20% serial dilutions) to concentrations across the measuring range of each analyte and matrix. Linear regression was performed on results of all test points using expected values calculated based on stocks sample dilution. Results are shown below.

Serum Linearity Results

	Na^+	K^+	Cl^+
Range	70-200	1-20	70-200
y-Intercept	-12.8	-0.04	5.39
m	1.04	1.01	0.97
R^2	1.00	1.00	1.00
Standard Error	3.5	0.3	2.1
Observations	39	66	39

Urine Linearity Results

	Na^+	K^+	Cl^+
Range	10-200	1-100	10-200
y-Intercept	1.11	0.15	-0.26
m	1.01	1.02	1.02
R^2	0.99	1.00	1.00
Standard Error	5.5	0.9	2.7
Observations	33	69	39

c. Comparison Studies:

Comparison studies were conducted using Diamond Tokyo Boeki ISE Module Calibrators and the predicate Tokyo Boeki ISE Module Calibrators on the Biolis 24i. Samples of both matrices, serum and urine, which spanned the reportable range was used. The results are summarized below.

Serum Correlation Results			
	Na^+	K^+	Cl^+
Range	70-200	1-20	70-200
y-Intercept	-1.6	0.49	2.87
m	1.00	1.01	0.96
R^2	0.9969	0.9971	0.9955
Standard Error	2.5	0.3	2.6
Observations	33	57	39

Urine Correlation Results			
	Na^+	K^+	Cl^+
Range	10-200	1-100	10-200
y-Intercept	-1.3	0.44	2.65
m	0.99	0.98	0.96
R^2	0.9976	0.9998	0.9939
Standard Error	2.7	0.4	3.7
Observations	42	62	73

d. Stability:
Accelerated (high temperature) stress test was conducted to support stability claim. Heat stressed reagents showed that calibrator parameters remained within specification thereby demonstrating stability equivalent to Tokyo Boeki calibrators.

Traceability:

All testing for analytes were conducted using Standards prepared from NIST salts. Testing was also conducted using reference methods.

Analyte	Standard Used for Determination of Analyte Value	Instrument Used
Na, K,	NIST 919a, 918a	iL 943 (Flame Photometry)
Cl	NIST 919a	Corning 925, SAT-500 Salt Analyzer (Titrimetric)

Expected Values (Controls, Calibrators, or Methods),

Target values, (or specifications) were obtained by testing reagents analytically prior to bottling, adjusting if necessary to meet specifications, testing analytically during the bottling process and prior to release to stock for distribution.

Conclusion:

Based on the results submitted in this pre market notification Diamond Tokyo Boeki ISE Module Calibrators are substantially equivalent to the Tokyo Boeki ISE Module Calibrators in Composition, Intended use, Packaging, and Storage for the measurement of Na^+, K^+, and Cl^-.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Diamond Diagnostics Inc
Ms. Kathy Cruz
Manager, Quality Assurance
Diamond Diagnostics Inc (USA)
333 Fiske Street
Holliston, MA 01746

APR 17 2012

Re: k120591
Trade/Device Name: Diamond Calibrators for Tokyo Boeki ISE Module Calibrators
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: February 24, 2012
Received: February 28, 2012

Dear Ms. Cruz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): _____

Device Name: Diamond Calibrators for Tokyo Boeki ISE Module Calibrators

Indications for Use:

Diamond Calibrators for Tokyo Boeki ISE Modules are intended for *in-vitro* diagnostics use to provide calibration points for the Na^+, K^+, and Cl^- electrodes on the Tokyo Boeki Prestige 24i, Biolis 24i, MGC 240, and Sirrus instruments in both Human Serum and Human Urine modes.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120591